

JUL 11 2006

## Smith &amp; Nephew Competitor Unicondylar Tibial Baseplate Components

SUBMITTER'S NAME: Smith & Nephew, Inc., Orthopaedic Division  
SUBMITTER'S ADDRESS: 1450 East Brooks Road, Memphis, TN 38116  
SUBMITTER'S TELEPHONE NUMBER: 901-399-6707  
CONTACT PERSON: Gino J. Rouss  
DATE SUMMARY PREPARED: April 10, 2006  
TRADE OR PROPRIETARY DEVICE NAME: Smith & Nephew Competitor Unicondylar Tibial Baseplate Components  
COMMON OR USUAL NAME: Knee Prosthesis  
CLASSIFICATION NAME: Knee joint femorotibial metal/polymer non-constrained cemented prosthesis, 21 CFR 888.3520  
DEVICE CLASS: Class II  
PANEL CODE: HSX Orthopedics Panel/87

**A. INTENDED USE:**

The Competitor Unicondylar Tibial Baseplate Components are indicated for restoring either compartment of a knee that has been affected by the following:

- Noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis;
- correction of functional deformity;
- revision procedures where other treatments or devices have failed; and
- treatment of fractures that are unmanageable using other techniques

The baseplate components are single use only and are intended for implantation only with bone cement.

**B. DEVICE DESCRIPTION:**

New unicondylar knee tibial baseplate components have been designed and developed by Smith & Nephew Orthopaedics. The subject devices are metal-backed tibial baseplates that are designed to be used with specific articular inserts. The overall designs of the components are based upon the existing Genesis Unicompartmental tibial implants subject of K912735.

**C. SUBSTANTIAL EQUIVALENCE INFORMATION:**

The Smith & Nephew Competitor Unicondylar Tibial Baseplate Components are similar to the following commercially available devices regarding design features, overall indications, and materials:

- Smith & Nephew Genesis Unicompartmental Knee System (K912735)
- Smith & Nephew Unicondylar Femoral Component (K030301)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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Smith & Nephew, Inc.  
Orthopaedic Division  
% Mr. Gino J. Rouss  
Regulatory Affairs Specialist  
1450 Brooks Road  
Memphis, Tennessee 38116

Re: K061011

Trade/Device Name: Competitor Unicondylar Tibial Baseplate Components  
Regulation Number: 21 CFR 888.3520  
Regulation Name: Knee joint femorotibial metal/polymer non-constrained cemented  
prosthesis  
Regulatory Class: Class II  
Product Code: HSX  
Dated: April 10, 2006  
Received: April 12, 2006

Dear Mr. Rouss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a stylized flourish at the end.

Mark N. Melkerson

Director

Division of General, Restorative  
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K061011

Device Name: Competitor Unicondylar Tibial Baseplate Components

### Indications for Use:

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Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use             
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of General, Restorative,  
and Neurological Devices

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